

Office Action Summary

Application No.

10/528,684

Applicant(s)

FLECKENSTEIN ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11-27 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 28 is/are rejected.
- 7) ☒ Claim(s) 3-10 is/are ~~objected to~~ will not be examined (See office action on page 2).
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3-21-05; 5-9-07</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-29 are presented for examination.

Applicants' preliminary amendment filed March 21, 2005 and the information disclosure statements filed March 21, 2005 and May 7, 2007 have been received and entered.

Applicants' election filed May 18, 2007 in response to the restriction requirement of April 30, 2007 has been received and entered. The applicants elected the invention described in claims 1-10 and 28 (Group I) with the elected species of formula II in claim 2 with traverse.

Applicants' traverse is not deemed persuasive for reasons set forth in the Office action dated April 30, 2007; therefore, the restriction requirement is hereby made Final.

Claims 11-27 and 29 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Claims 3-10 will not be examined because they contain non-elected subject matter (species).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (I) or (II) or the pharmaceutically acceptable salt, does not reasonably provide enablement for a pro-

Art Unit: 1614

drug or metabolite of the compound of formula (I) or (II). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims recite “A compound ... or a pharmaceutically acceptable salt, **pro-drug or metabolite** thereof” wherein there is insufficient description in the specification regarding the types of **pro-drug or metabolite** intended by the recitation. The term “pro-drug” generally represents any type of ester, amide, active metabolite, residue, etc. of a compound, which is transformed to an active agent *in vivo*. In the instant case, the specification does not provide what ‘type of pro-drugs or metabolites’ of the compounds of formula (I) or (II) are intended. The structural formula in each of the claim is a specific structural representation having specific defined substituent groups. There is no disclosure regarding any metabolite of the compounds of formula (I) or (II) disclosed in the specification. A ‘pro-drug’ is any compound which is pharmaceutically active *in vivo* when it undergoes transformation and the specification does not provide any disclosure of what these compounds might be that *in vivo* transform in to the instantly claimed compounds.

Since the structural formulae already include ester and amide functional groups, deletion of the terms “pro-drug or metabolite thereof” will obviate the rejection.

Claims 1, 2 and 28 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Epstein et al. (US 2002/0103162 A1).

Epstein et al. teach the use of threo-methylphenidate compound to enhance memory wherein the compounds are derived from formula (I) or formula (I) (see [0007]-[0023] and [0042]-[0050]. Note particular to section [0214] which states the compounds learning and memory defects such as age-associated memory impairment and dementia resulting from Parkinson's disease. Note Parkinson's disease can cause dementia: a later development starting with slowing of thought and progressing to difficulties with abstract thought, **memory**, and behavioral regulation (see the enclosed http://en.wikipedia.org/wiki/Parkinson's_disease on page 4). Finally, note in section [0261] teaches the dosage range of the active agents is from about 0.0001 to about 100 mg per kilogram of body weight per day; note applicants' dosage range of between 5 and 40 mg/kg is within its range.

Clearly, the cited reference teaches every limitation of the instant invention; therefore, the instant invention is unpatentable.


Claims 1, 2 and 28 are not allowed.

The remaining reference listed on the enclosed PTO-892 is cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kevin E. Weddington
Primary Examiner
Art Unit 1614

Application/Control Number: 10/528,684

Page 6

Art Unit: 1614

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June 7, 2007